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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/399,083	09/17/1999	DAVID CALDERWOOD	BBI-6043CCPCPA	1842

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EXAMINER

RAO, DEEPAK R

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/399,083

Applicant(s)
Calderwood et al.

Examiner
Deepak Rao

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1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 25, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 11, and 46-52 ☒ are pending in the application.
- 4a) Of the above, claim(s) 11 and 48-51 ☒ are withdrawn from consideration.
- 5) ☒ Claim(s) 52 ☒ is/☒ are allowed.
- 6) ☒ Claim(s) 1-8, 10, 46, and 47 ☒ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

This office action is in response to the amendment filed on November 25, 2002.

Claims 1-8, 10-11 and 46-52 are pending in this application.

Election/Restriction

The claims have been examined based on applicant's election of the species N-(4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-fluorophenyl)-2-(trifluoromethoxy)-1-benzenesulfonamide (as indicated in paper no. 21). Claims 1-8, 10, 46, 47, and 52 read on the elected species. As the elected species was not found, the search and examination was expanded to compounds of structural formula of claim 1 wherein ring A is substituted phenyl; L is -NH-SO₂-; j is 0; R₃ is substituted phenyl; R₂ is H; and R₁ is cyclopentyl and art was found.

Claims 11 and 48-51 are withdrawn from further consideration as being drawn to nonelected species (see MPEP § 803.02) pursuant to 37 CFR 1.142(b). Claims 1-8, 10, 46, 47 and 52 are considered to the extent readable on the examined subgenus and all other definitions of the variables and the other species are withdrawn as being drawn to nonelected species.

The following rejections of the previous office action are withdrawn:

1. The rejection of claims 1-8 and 10 under 35 U.S.C. 112, first paragraph of the previous office action is hereby rendered moot in view of the amendment to claim 1.

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(Note: The terms “-NHC(O)R₁₃₀-” and “-NHSO₂R₁₃₀-” remain in claim 50, however, this claim has been withdrawn from consideration as it does not read on the elected species.)

2. The rejection under 35 U.S.C. 103(a) (based on 35 U.S.C. 102(e)) of claims 1-8, 10 and 46-47 over Calderwood et al., U.S. Patent No. 6,001,839 is withdrawn in view of applicant's statement of Common Ownership.

3. The objections to claims 1 and 6 of the previous office action are withdrawn in view of applicant's amendments.

The following rejections are maintained:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claim 46 is rejected over Calderwood et al., WO 98/41525, for the reasons set forth in the previous office action which are incorporated here by reference. As explained in the previous office action(s), the reference teaches 4-amino-7H-pyrrolo[2,3-d]pyrimidin-5-yl compounds having an optionally substituted phenyl as the 5-substituent which is further attached to -A-R₅ wherein A is -NH-SO₂- and R₅ is optionally substituted phenyl, etc., see the structural formula (I) and the specific compounds in page 14, at lines 9-14 and 22-23. The instant claim differs by reciting specific species that falls within the reference genus, see e.g., the species N-(4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-chlorophenyl-1-benzenesulfonamide (lines 12-13), which differs from the reference disclosed compound by having chloro substituent in place

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of the methoxy substituent of the reference (see e.g., page 14, lines 9-10). The reference, however, teaches that the phenyl ring of R₃ to be substituted by any substituents selected from alkoxy, halo, etc. (see page 3, lines 26-28) and therefore, teaches the equivalency of the substituents. Further, the reference compounds are also used as pharmaceutical agents having tyrosine kinase inhibitory activity. Therefore, there is sufficient motivation to one of ordinary skill in the art to select any of the compounds falling within the reference disclosed genus with the reasonable expectation of obtaining compounds having similar properties and therefore, the same use as taught for the reference compounds.

Applicant's arguments based on *In re Grabiak* have been fully considered but they were not deemed to be persuasive. The situation in *Grabiak* was different from the instant application because the references in that case did not provide evidence to substitute sulfur for oxygen, and therefore, the court concluded that 'there must be adequate support in the prior art for the ester/thioester change in structure, in order to complete the *prima facie* case'. The instant scenario is different because the reference clearly teaches the equivalency between the various substituents in that any of the substituent from the list provided can be selected to be substituted on the phenyl group and further the reference provides examples of such substituted phenyl groups and thus, provides sufficient motivation to one of ordinary skill in the art to use any of the substituents on the phenyl group. Therefore, for all the reasons of record, in the absence of unexpected properties, it is maintained that the instantly claimed compounds are obvious over the prior art disclosure.

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2. Claims 1-8, 10 and 46-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,001,839, for the reasons provided in the previous office action which are incorporated here by reference.

Applicant did not present any arguments for this rejection. It is acknowledged that a terminal disclaimer may be filed in the near future once the new assignment documents reflecting the transfer of ownership are recorded.

The following rejections are under new grounds:

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. Claim 6 recites the limitation "substituted amino" in line 5. There is insufficient antecedent basis for this limitation in claim 1 on which claim 6 depends from. The substituent list for 'Ring A' in claim 1 includes a moiety -NR₄R₅ wherein R₄ and R₅ are as specifically defined in the claim. The instant recitation on the other hand is broader than

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the $-NR_4R_5$ of the base claim and represents any 'substituted amino' including those not contained in the definition provided in claim 1 and therefore, lacks antecedent basis.

2. Claim 6 recites the limitation "substituted tetrazolyl" in lines 5-6. There is insufficient antecedent basis for this limitation in claim 1 on which claim 6 depends from. The substituent list for 'Ring A' in claim 1 includes a moiety 'tetrazolyl', however, the instant recitation of 'substituted tetrazolyl' is broader than the recitation in base claim.
3. Claim 6 recites the limitation "-S-(substituted or unsubstituted heteroaryl)" in lines 6-7. There is insufficient antecedent basis for this limitation in claim 1 on which claim 6 depends from. The substituent list for 'Ring A' in claim 1 does not contain the above recited moiety.
4. Claim 6 recites the limitation " R_c " as a substituent to be substituted on Ring A, see line 8. There is insufficient antecedent basis for this limitation in claim 1 on which claim 6 depends from. The definition provided for ' R_c ' in claim 6 includes several groups such as 'hydrogen, $-W-(CH_2)_t-NR_dR_e, \dots$ ' are not part of the substituent list for 'Ring A' in claim 1 and the inclusion of the term is broader than the recitation in base claim. For example, when ring A is substituted with one R_c which is hydrogen, i.e., the ring becomes unsubstituted. However, claim 1 specifically requires "one of more substituents selected from the group consisting of a substituted or unsubstituted aliphatic group,..." and therefore, the instant limitation lacks antecedent basis. Similarly, when R_c is a group containing W, the substituents extend beyond those listed in claim 1.

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Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 6 and 7 are rejected under 35 U.S.C. 102(a) as being anticipated by Calderwood et al., WO 98/41525 (published September 24, 1998). The instantly claimed compounds read on the compounds of the reference, see formula (I) and the species, e.g., page 14, lines 9-14, 22-23, etc. The instant claims include ring A to be substituted by R_c which is defined to be -W-(CH₂)_t-O-alkyl or -W-(CH₂)_t-OH wherein W is a bond and t is 0, which compounds are identical to the reference disclosed compounds.

2. Claims 6 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Calderwood et al., U.S. Patent No. 6,001,839 (filed March 17, 1998). The instantly claimed compounds read on

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the compounds of the reference, see formula (I) and the species, e.g., col. 10, lines 5-15, 26-27, 30-31, etc. The instant claims include ring A to be substituted by R_c which is defined to be $-W-(CH_2)_t-O-alkyl$ or $-W-(CH_2)_t-OH$ wherein W is a bond and t is 0, which compounds are identical to the reference disclosed compounds.

Note: Applicant can not rely on the 35 U.S.C. 119(e) or 120 priority claims based on the Provisional or Non-provisional Applications to overcome the above rejections because the prior application do not fully provide support for the instant claims, see the definitions of the variables A, L, etc. in formula (I). Accordingly, the effective filing date for the instant claims is the filing date of the instant application, i.e., September 10, 1999.

Claim Rejections - 35 U.S.C. § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8, 10 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calderwood et al., WO 98/41525. The reference teaches a generic group of compounds which is analogous to the instantly claimed compounds. See formula I in page 2 wherein R_3 is represented by formula (a) wherein the phenyl ring of formula (a) is optionally further substituted (see page 3, lines 6-9); A is $NHSO_2$ (page 3, line 10) and R_5 is optionally substituted phenyl. The reference further discloses several species that fall within the above genus, see pages 10-14, particularly page 14, lines 9-14 and 22-23. The compounds are taught to be useful as pharmaceutical

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therapeutic agents having protein kinase inhibition activity, see the entire document. Claims 6 and 7 are anticipated by the reference, see the rejection under 35 U.S.C. 102. The remaining claims differ from the reference by structurally analogous compounds, i.e., the instant claims recite a substituent such as alkyl, halo, etc. on Ring A, however, the reference teaches that the phenyl group of R_3 may be substituted by any of the substituents provided in the list at page 3, lines 26+. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as pharmaceutical therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

Allowable Subject Matter

Claim 52 is allowed. The closest references of record, US'839 or WO'525 do not teach or fairly suggest the instantly claimed species, wherein the second phenyl ring is substituted with a 2-OCF₃. The reference does not teach that the phenyl ring of R_5 be substituted with a haloalkoxy group.


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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Deepak Rao
Primary Examiner
Art Unit 1624

February 9, 2003